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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER

LUKTON, DAVID

ART UNIT PAPER NUMBER

1654

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,462

Applicant(s)

DEPABLO ET AL.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-30, 32 and 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants' election of Group IV (claims 31-33) is acknowledged. Also acknowledged are the species elections, i.e., a composition in which trehalose is present at a concentration of 45 mM, and the phosphate is present at a concentration of 45 mM.

Applicants have traversed the restriction by arguing that no significant burden would be placed on the examiner by examining all of the claims. However, the examiner disagrees. In particular, numerous compounds would qualify as "polyhydroxy compounds". For example, virtually all proteins would qualify, given the serines and threonines. In addition, all polysaccharides would qualify. Furthermore, to the extent that claim 31 is novel, an important component of that novelty is the limitations on concentration of the "polyhydroxy compound" and the phosphate. By reciting weight rather than molarity, claim 1 for example extends the range of concentrations of the "polyhydroxy compound". And claims such as claim 1 vastly extend the range of concentrations of the phosphate ions relative to what is permitted in claim 31. A given "polyhydroxy compound" can have several hundred hydroxyl groups, or just two. In addition, the term "phosphate ions" is not limited to inorganic phosphate. Thus, compounds such as ATP, polynucleotides, and phosphorylated proteins would qualify. As matters currently stand, however,

the restriction requirement is maintained. Notwithstanding the foregoing, the possibility of rejoining a limited form of claim 34 is not precluded.

Claim 32 is withdrawn from consideration, as the elected composition does not contain such. Claims 1-30 and 34-37 are withdrawn pursuant to the restriction.

Claims 31 and 33 are examined in this Office action.



Claim 31 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6653062. Although the conflicting claims are not identical, they are not patentably distinct from each other.

There is overlap of the claimed compositions. The molecular weight of trehalose is about 342 g/mol. Thus, for example, a concentration of trehalose of 10% w/w would correspond to a concentration of about 290 mM. In addition, the "polyhydroxy compound" need not be limited to trehalose, and as such a broad range of molecular weights would be encompassed.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).



Claim 31 is objected to on grammatical grounds. This claim recites the following:

“at least one polyhydroxy compound, where the concentration polyhydroxy”

First, ”where” should instead be *wherein* since a “polyhydroxy compound” is not a geographical location. Second, a preposition should presumably follow the word “concentration”.



Claims 31 and 33 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 is rendered indefinite because it requires, on the one hand, that the medium be aqueous, but on the other hand, permits water to be absent. Thus, is water required to be present or is it not?



The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 31 is rejected under 35 U.S.C. §102(b) as being anticipated by Spargo (USP 5,736,313).

Spargo discloses (e.g., col 8, line 25) a composition that comprises 139 mM sucrose and 55 mM phosphate together with platelets.

Thus, the claim is anticipated.



Claim 31 is rejected under 35 U.S.C. §102(b) as being anticipated by Yuasa (USP 5,753,428).

Yuasa discloses (e.g., col 8, line 40+) a composition that comprises 5-100 mM glycerol and 10-50 mM phosphate together with platelets.

Thus, the claim is anticipated.



No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800